Application No.: 09/851,606 Docket No.: 273012011700

#### **REMARKS**

Claims 1-23, 26-28 and 30 are pending after the present amendments. Claim 12 has been amended to correct obvious typographical errors, and does not contain new matter.

## Rejections under 35 U.S.C. § 112

Claims 1-28 and 30 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Specifically, the Office alleged that steps leading to the formation of different products (*i.e.*, micelles, vesicles, emulsion, gel and matrix) are missing in the claim. Applicants respectfully disagree, and address the rejection in view of the pending claims.

The requirement under 35 U.S.C. § 112, second paragraph is evaluated in the context of whether the claim is definite - *i.e.*, whether the scope of the claim is clear to one possessing the ordinary level of skill in the art. MPEP § 2171. Applicants respectfully submit that it is known in the art that the nature of the hydration product formed is affected by the nature of the poloxamer carrier agent. As described in the specification, poloxamers may be emulsion forming, micelle forming, and water soluble which form an extended network in solution. At higher concentrations, poloxamers have a tendency to undergo gel formation under certain temperature conditions. (Specification at page 33, lines 8-12.)

Because the claims are clear and definite, Applicants respectfully request that this rejection be withdrawn.

### **Double Patenting**

Claims 4-7, 16-18, 26-28 and 30 are rejected under obviousness-type double patenting, as allegedly being unpatentable over claims 1-13 of U.S. patent no. 6,693,093. To expedite prosecution, Applicants submit a terminal disclaimer, thereby obviating this rejection.

sd-326724 6

Application No.: 09/851,606 Docket No.: 273012011700

# Rejections under 35 U.S.C. § 103

Claims 1-28 and 30 are rejected under 35 U.S.C. § 103(a), as allegedly being unpatentable over Schneider (6,258,378), alone or in combination with Lyons (5,616,342) and Young (6,375,930). Claims 1-10, 16-28 and 30 are also rejected under 35 U.S.C. § 103(a), as allegedly being unpatentable over Lyons, in combination with Klaveness (5,674,468). Furthermore, claims 1-10, 16-28 and 30 are rejected under 35 U.S.C. § 103(a), as allegedly being unpatentable over Lyons, in view of Desai (6,074,666) or Madden (5,389,378) in further combination with Unger (6,028,066). Applicants respectfully disagree.

Nonetheless, to expedite prosecution without acquiescing to the Examiner's arguments, the claims have been amended to recite particular poloxamer carrier agents which comprise varying amounts of propylene oxide and ethylene oxide. (In the numeric naming system for the PLURONIC® series and the Synperonic® series of poloxamers, the last digit of the copolymer number multiplied by 10 gives the approximate percent molecular weight of ethylene oxide. In addition, in at least the PLURONIC® series, the first two digits of the copolymer number multiplied by 100 represent the approximate percent molecular weight of the propylene oxide block.)

The references are silent regarding the recited poloxamers. Because the cited art, alone or in combination, fail to teach or suggest the invention as claimed, the claims are nonobvious. Applicants therefore, respectfully request that this rejection be withdrawn.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

sd-326724 7

Application No.: 09/851,606 Docket No.: 273012011700

## **CONCLUSION**

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket

No. 273012011700. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: July 26, 2006

Respectfully submitted,

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